

510(k) Summary

Pursuant to 21CFR807.92(c), Quest Medical Inc. provides the following Summary Statement for this Premarket Notification.

- A. Quest Medical, Inc.
One Allentown Parkway
Allen, TX 75002 USA
972-390-9800 / 800-627-0226; Fax 972-390-2881
Amy Clendening-Wheeler
July 31, 2012
- B. Trade/Device name: STENTube® Lacrimal Intubation Set
Product Code: OKS
Device Classification Name: Lacrimal Stents and Intubation Sets
Regulatory Class: Unclassified
- C. Predicate Device:
Ryder International Lacrimal Intubation Set, K962151
- D. The Quest Medical, Inc. STENTube is a sterile, hand held, ophthalmic surgical device. The STENTube is a large diameter lacrimal intubation set consisting of two malleable stainless steel probes (to facilitate insertion) securely attached to a flexible silicone tube. The STENTube intubation set is single-use, biocompatible, and non-pyrogenic. The STENTube is packaged with 1 device per pouch, and 2 pouches per carton. It is available by prescription only. The STENTube is used following a procedure in the lacrimal system, such as a Dacryocystorhinostomy (DCR), to clear any blockage to the lacrimal passage. The tubes are inserted with the purpose of keeping the passages open for a period of time during the healing process.
- E. The intended use and the Indications for use for the STENTube are the same as for the Predicate device, with the exception of an update to the device name.

Intended Use

The STENTube lacrimal intubation device is a sterile, single-use, prescription device intended for use as an *in situ* (up to 11 months) device for various ophthalmic procedures.

Indications for Use

The STENTube lacrimal intubation device is indicated for use for the following:

1. Maintenance of lacrimal outflow post-primary DCR surgical procedure

2. Maintenance of lacrimal outflow post-failed open DCR surgical procedures with complete obstruction
 3. Reconstruction of the canaliculi
- F. Technological Characteristics: The STENTube has the same technological characteristics compared to the predicate device. It has the same design and materials. Only the length of some of the components has been modified, and a shrink tube component was added. Sterilization method has been updated and the shelf life extended to 3 years.
- G. Non-clinical Performance Data: There was no additional testing required as a result of the Risk Assessments performed for the modification to the STENTube. Verification and Validation tests were performed to ensure the modified STENTube continued to meet or exceed specification in accordance to the Design Requirements. Those specifications are the same as for the predicate device. There were no clinical tests performed. The bench-testing concluded that the modified device, the STENTube, performed as well or better than the predicate device. Testing for the STENTube demonstrates it is as safe and as effective as the predicate device.
- H. Information Verification.
This summary statement:
- a. Includes only information that is also covered in the body of the 510(k);
 - b. Does not contain any puffery or unsubstantiated labeling claims;
 - c. Does not contain any raw data, i.e. contains only summary data;
 - d. Does not contain any trade secret or confidential commercial information;
 - e. Does not contain any patient identification information.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

JUL 31 2012

Quest Medical, Inc.
c/o Ms. Amy Clendening-Wheeler
Sr. Regulatory Affairs Specialist
One Allentown Parkway
Allen, Texas 75001

Re: K113118

Trade/Device Name: STENTube® Lacrimal Intubation Set
Regulation Name: Lacrimal Stents and Intubation Sets
Regulatory Class: Unclassified
Product Code: OKS
Dated: June 29, 2012
Received: July 02, 2012

Dear Ms. Clendening-Wheeler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

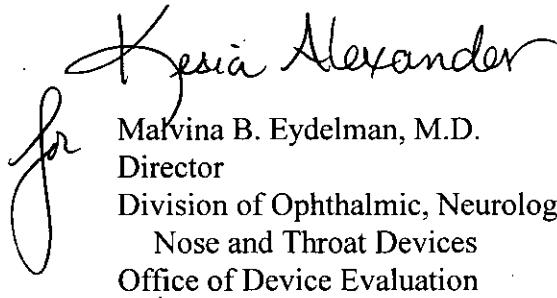
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


for
Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use510(k) Number (if known): K113118Device Name: STENTube® Lacrimal Intubation Set

Indications for Use: The STENTube Lacrimal Intubation Set is indicated for the following:

1. Maintenance of lacrimal outflow post-primary DCR surgical procedure
2. Maintenance of lacrimal outflow post-failed open DCR surgical procedures with complete obstruction
3. Reconstruction of the canaliculi

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat DevicesPage 1 of 1510(k) Number K113118